MAY 11 2000

K000706

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February 28th, 2000

Subject:	510(k) Summary of Safety and Effectiveness Information for the Datex-Ohmeda Aestiva/5 with 7100 Ventilator Anesthesia System
Proprietary:	Datex-Ohmeda Aestiva/5 with 7100 Ventilator Anesthesia System
Common:	Gas Machine, Anesthesia
Classification:	Anesthesiology, 73CBK, 21CFR868.5160

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Aestiva/5 with 7100 Ventilator Anesthesia System is substantially equivalent to the following currently marketed device:

1. Datex-Ohmeda Aestiva 3000 Anesthesia System - Class II - 21CFR868.5160
2. Ohmeda 7900 Ventilator – Class II - CFR868.5895

The Aestiva/5 Anesthesia Gas System with 7100 Ventilator is a gas machine that supplies set flows of medical gases to the breathing system. A large selection of frames, gases, and vaporizers give full control of the system configuration. The Aestiva/5 with 7100 is available in wide or narrow trolley and pendant models. The narrow trolley and pendant come with two or three gases, two vaporizer positions and up to four cylinder connections. The wide trolley comes with two, three or four gases, three vaporizer positions and up to five cylinder connections. All models have O2 and N2O. The Aestiva/5 with 7100 comes with up to two optional gases (air, CO2, heliox). All Aestiva systems accept Tec 4, Tec 5 and Tec 6 vaporizers. Safety features and devices within the Aestiva/5 with 7100 decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

The 7100 Ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator with a build in monitoring system for inspired oxygen, airway pressure and exhaled volume. Sensors in the breathing circuit are used to control and monitor patient ventilation as well measure inspired oxygen concentration. This allows for the compensation of compression losses, fresh gas contribution and small leakage in the breathing absorber, bellows and system. User setting and microprocessor calculations control breathing patterns. User interface keeps settings in memory. The user may change settings with a simple and secure setting sequence. A bellows contains breathing gasses to be delivered tot he patient. Positive End Expiratory Pressure (PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs in outward. An RS-232 serial digital communications port connects to and communicates with external devices.

The Aestiva/5 with 7100 Ventilator was designed to comply with the applicable portions of the following voluntary standards;

1. EN 740 - Anesthetic Work Stations
2. EN 60601-1, IEC 601-1: 1988 - Medical Electrical Equipment
3. EN 60601-1-2, IEC 601-1-2: 1998 - Medical Electrical Equipment - Electromagnetic Compatibility
4. EN 475 – Electrically Generated Alarm Signals
5. ISO 5358 - Anesthetic Gas Machines
6. ASTM F1208-94 – Anesthesia Breathing Circuit Standard
7. ASTM F1101-90 – Standard Specification for Ventilators Intended for Use During Anesthesia

The Datex-Ohmeda Aestiva/5 with 7100 Ventilator and the currently marketed devices are substantially equivalent in design concepts, technologies and materials. The Datex-Ohmeda Aestiva/5 with 7100 Ventilator has been validated through rigorous testing that, in part, support the compliance of Aestiva/5 with 7100 Ventilator to the above mentioned standards.

Datex·Ohmeda

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Mr. Daniel Kosednar
Datex-Ohmeda
Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550

Re: K000706
Datex-Ohmeda Aestive/5 Anesthesia System with
7100 Ventilator
Regulatory Class: II (Two)
Product Code: 73 BSZ
Dated: April 14, 2000
Received: April 17, 2000

Dear Mr. Kosednar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000706

Device Name: Datex-Ohmeda Aestiva/5 with 7100 Ventilator Anesthesia Gas System

Indications For Use:

The Aestiva/5 Anesthesia Gas System with 7100 Ventilator is a gas machine that supplies set flows of medical gases to the breathing system. A large selection of frames, gases, and vaporizers give full control of the system configuration. The Aestiva/5 with 7100 is available in wide or narrow trolley and pendant models. The narrow trolley and pendant come with two or three gases, two vaporizer positions and up to four cylinder connections. The wide trolley comes with two, three or four gases, three vaporizer positions and up to five cylinder connections. All models have O2 and N2O. The Aestiva/5 with 7100 comes with up to two optional gases (air, CO2, heliox). All Aestiva systems accept Tec 4, Tec 5 and Tec 6 vaporizers. Safety features and devices within the Aestiva/5 with 7100 decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

for (Division Sign-Off)
Division of Cardiovascular, Respiratory, and
Neurological Devices

510(k) Number: _____

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801.109) (Optional Format 1-2-96)